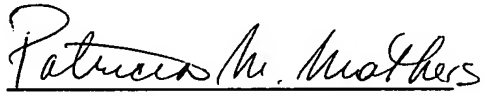
Remarks:

1. **Amendments to the Specification:** The specification was amended to better conform to the conventions and formalities required or preferred by the USPTO. No new subject matter was introduced into the specification. A Literal Translation of the originally filed specification is being filed concurrently with this paper. A Substitute Specification and a Specification showing all deletions and insertions relative to the literal translation of the specification as orignally filed are included with this paper.

2. **Amendments to the Claims:** Claim 1 – 4 were cancelled and new claims 5 – 10 added. The subject matter of claim 5 is disclosed in paragaph [0006], that of claims 6 – 9 in paragraph [0008]; and that of claim 10 in paragraph [0007] of the Substitute Specification. No new subject matter has been introduced with these new claims and Applicants respectfully request approval and entry of the claims.

Respectfully submitted,



Date: May 19, 2006

Enclosed:
Substitute Specification
Subst. Spec. showing Amendments

Patricia M. Mathers
Attorney for Applicants
Reg. No. 44,906
Bohan, Mathers & Associates, LLC
P. O. Box 17707
Portland, ME 04112-8707
Tel: 207 773 3132
Fax: 207 773 4585
Email: pmm@bohanmathers.com

EXTRACORPOREAL STORAGE OF ORGANS

BACKGROUND INFORMATION

[0001] FIELD OF THE INVENTION

[0002] The invention relates to ~~an arrangement~~ a system for extracorporeal storage of organs for artificially preserving or regenerating the vital functions of organs intended for transplant surgery. ~~which in a manner that is prior art artificially maintains or regenerates the vital functions of organs. As used herein, the term organ also includes limbs and tissue lobes and the like; hence, organ is used as a generic term.~~ An important field of use is, in particular, the transport of organs or, ~~furthermore~~ generally, biochemical or pharmacological ~~examinations in~~ study of isolated organs.

[0003] DESCRIPTION OF THE PRIOR ART

[0004] As used herein, the term "organ" shall also include limbs and tissue lobes and the like; hence, "organ" is used as a generic term. Devices for the perfusion of isolated organs are ~~prior art~~ known.

[0005] Schoen, M. R. ~~uses such~~ discloses a perfusion device ~~with such~~ that is a fluid-filled, closed organ perfusion chamber with cyclic pressure fluctuations for ~~normothermic~~ normothermal extracorporeal liver perfusion. See: ~~(~~"Transplantation von Lebern nicht-herzschlagender Spender im Schweineleber-Transplantationsmodell," Habilitationsschrift 1999, Humboldt ~~Universität~~Universitaet zu Berlin~~)~~. Water heated to about 37 degrees C in an external heat exchanger flows through the organ perfusion chamber. This

circulation is needed, in addition to the perfusion circulation and the dialysate circulation.

BRIEF SUMMARY OF THE INVENTION

[0006] It is the aim of the present invention to provide the simplest possible construction of a system ~~a design of a device as simple as possible~~ for the extracorporeal storage of organs. In organ transplant ~~transplantation~~ surgery, organ and transplant logistics has become in part a global operation and transporting and preserving the functional ability of the organs is a particularly important task of logistics. ~~particularly, the transport and maintenance of the functional ability of the organs is an important task of organ and transplantation logistics with partly global operation~~.

[0007] According to the invention, this object is achieved by providing a storage system for extracorporeal storage of organs comprising an organ perfusion chamber with a temperature control device.~~attained by the distinguishing features of the main claim. Other useful embodiments of the invention result from the following claims. The arrangement for the extracorporeal storage of organs according to the invention consists at least of an organ perfusion chamber with a controllable temperature device.~~

[0008] An organ, covered by a protective cover, is stored in the organ perfusion chamber. The protective cover is preferably ~~executed as~~ an impermeable plastic bag. The organ thus protected in this manner is maintained in a completely floating state in the storage fluid.

[0009] The underlying concept of the invention is to use as the storage fluid the dialysate, which is already available. ~~The invention is based on the conception to use the dialysate which is already available as storage fluid.~~ The dialysate is an essential ~~important~~ component for preserving ~~maintaining~~ the vital functions of the organ and as such is also an essential ~~important~~ component of the circulation systemfor preserving vitality. ~~vital-state maintaining circuit, which is composed of~~ This circulation system comprises a dialysate circulation and a perfusate circulation which supply ~~for supplying~~ the extracorporeal organ. According to the invention, the required dialysate circulation and the necessary aggregates ~~apparatuses needed for it~~ are used to integrate the storage fluid as dialysate in the dialysate circulation and at the same time to use the organ perfusion chamber as a reservoir for the dialysate.

[0010] The organ perfusion chamber is hermetically sealed against ~~closed tight to~~ liquid and pressure. Not only is it important for medical reasons to seal the chamber, but it also is particularly important to do so if the organ is to be transported by plane or helicopter. ~~In addition to the medical necessity, this makes transport by plane or helicopter possible, in particular.~~

[0011] The wall of the organ perfusion chamber, the protective cover and the dialysate are transparent. A ~~controllable~~ temperature control device provides the normothermi~~c~~al or hypothermi~~c~~al ambient temperature for the extracorporeal organ. The temperature control device is preferably in the form of a ~~executed as~~ heating mat that is placed on the floor ~~lining the bottom~~ of the organ perfusion chamber. The flow of the dialysate ensures that the isolated organ is maintained at an even temperature. In another preferred embodiment of the invention, the temperature device is integrated into the wall of the organ perfusion chamber as heating and cooling loops. Multiple measuring probes or sensors record

characteristics and parameters, such as, for example, fluid level, pressure, temperature. Signals from the probes or sensors may be made available for processing for presentation on a display device or for digital process control. ~~a uniform temperature of the isolated organ is maintained. In another preferred embodiment of the invention, the temperature device is integrated in the wall of the organ perfusion chamber as heating and cooling loops. Several measuring probes pick up characteristics and parameters of the circuit, for example, filling level, pressure, temperature and enable the processing of these signals for an indicating device or a digital process control.~~

BRIEF DESCRIPTION OF THE DRAWING

[0012] **Fig. 1** is a schematic illustration of a system according to the invention for the extracorporeal storage of an organ.

[0013] ~~With reference to the accompanying drawing, one example of the embodiment of the invention will now be described in detail.~~

DETAILED DESCRIPTION OF THE INVENTION

[0014] **FIG. 1** ~~Figure 1~~ schematically depicts an example of one embodiment of a storage system **100** for the extracorporeal storage of organs. The storage system ~~an arrangement for the extracorporeal storage of organs. The arrangement~~ comprises a transparent organ perfusion chamber **1**. The organ perfusion chamber is ~~closed~~ hermetically sealed against fluid and pressure with quick-release fasteners (not shown) ~~and is tight to fluid and pressure~~. In this embodiment, an organ **2** is stored at normothermal temperature in a storage fluid

4. The organ **2** shown in the illustration is a liver, but it is understood that the term organ is used herein broadly to refer to internal organs, as well as limbs, tissue lobes, and the like. As shown, a protective cover **21** within the organ perfusion chamber **1** receives and covers the organ **2**, effectively protecting it from the storage fluid **4**, yet allowing exposure to a vitality-preserving circulation system **5**. The protective cover **21** is, for example, an impermeable, transparent plastic bag. ~~a liver, as organ 2, is stored at normothermic temperature. The protective cover 21 is a impermeable, transparent plastic bag.~~

[0015] The covered organ 2 is maintained in a completely floating state in the ~~a~~ storage fluid 4. The storage fluid 4 is a dialysate and is a component of the vitality-preserving ~~vital-state maintaining~~ circulation system 5. A ~~controllable~~ temperature control device 3 is provided in the organ perfusion chamber 1. In this embodiment, the temperature control device **3** is a heating mat. Other suitable temperature control systems include heating or refrigeration loops integrated into the wall of the perfusion chamber **1**. ~~integrated as heating mat in the organ perfusion chamber 1~~. Multiple ~~Several~~ measuring probes or sensors 6 supply signals for a process control~~, and a~~. A fluid level indicator 61 indicates the level of the storage fluid 4. The fluid-level indicator **61** shown in the embodiment is a riser, which, for purposes of illustration, has been rotated 90 degrees. It is actually disposed vertically in the organ perfusion chamber **1** and extends perpendicular to the plane of the drawing sheet. ~~Disposed vertically on the organ perfusion chamber 1 is, by way of example, a riser as means of level indication 61. In Fig. 1, this riser has been turned through 90° in the plane of the sheet.~~

ABSTRACT

Storage system for extracorporeal storage of organs. The storage system artificially maintains or regenerates the vital functions of organs, including limbs and tissue lobes. The storage system comprises an organ perfusion chamber filled with dialysate as a storage fluid and equipped with a temperature control device that maintains the temperature of the storage fluid. The organ stored in the perfusion chamber is covered by a protective cover and maintained in a completely floating state in the storage fluid.

~~Summary~~

~~The invention relates to an arrangement for extracorporeal storage of organs. Such arrangements artificially maintain or regenerate the vital functions of organs, in which organs also comprise limbs and tissue lobes.~~

~~The arrangement for the extracorporeal storage of organs according to the invention consists at least of an organ perfusion chamber 1 with a controllable temperature device 3. Disposed in the organ perfusion chamber 1 is an organ 2 which is covered by a protective cover 21. The organ 2 protected in this manner is maintained in a completely floating state in the storage fluid 4. The invention is characterized essentially in that the storage fluid 4 is a dialysate, which is a component of the vital state maintaining circuit 5.~~

~~Fig. 1~~